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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,366	08/13/2003	Michael D. DeGould	112559.00002	8438

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/640,366	DEGOULD, MICHAEL D.	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/13/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1-24 are rejected.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the prevention of alveolar osteitis. The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) As to undue experimentation.

The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1) the nature of the invention; the invention is directed to a method for preventing alveolar osteitis and pain following tooth extraction.

2) the breadth of the claims; the scope of the method claims include the prevention of alveolar osteitis.

3) the predictability or unpredictability of the art; the art does not enable a person of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. The burden of enabling one skilled in the art to prevent alveolar osteitis and pain following tooth extraction would be much greater than that enabling the treatment. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing alveolar osteitis. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing alveolar osteitis.

No experimental evidence supporting preventing alveolar osteitis using the specified actives would actually prevent all alveolar osteitis by simply administering, by any method, an amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing the risk of alveolar osteitis after tooth extraction.

The term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not as of yet reasonably possible with most diseases/disorders. The specification is viewed as lacking an adequate enablement of where alveolar osteitis may be actually prevented.

4) the amount of direction or guidance presented; the specification and the example does not provide any guidance in terms of preventing alveolar osteitis.

5) the presence or absence of working examples; no working examples are provided for preventing alveolar osteitis after tooth extraction, for example in a patient, in the specification. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the preventative effects of the instant composition. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

6) the quantity of experimentation necessary; the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of preventing alveolar osteitis, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-6, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present

application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim1 is indefinite since it is incomplete because neither step (a) nor (b) contain indicia that filling a cavity and enclosing same "prevent" osteitis and pain. No component of the dressing is indicated as a pain reduction additive in the composition employed in the process of claim 1. None of claims 2 through 11 eliminate this issue.

Claim 6 is indefinite regarding "mixtures thereof" because it is not apparent what the components of the mixture are in terms which specific metals and which specific peroxides that would make up the mixture. See also claims 7,9, and 10. In addition, it is not clear from the claims whether or not metal cations means one cation selected from many is used in the composition or whether many cations are used simultaneously in the composition. This also applies to the "peroxides".

The term "maybe"(claim 12) is a relative term that renders the claim indefinite. The expression "maybe" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art

would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether it should or should not be used in an oral cavity and what degree of variability is within the scope of the claim. Furthermore, the Examiner has noted the presence of the term "collagen derivative" and "crosslinking agent" these terms are relative terms that render the claims indefinite. In particular, "derivative" does not particularly point out the degree or type of derivation that a given compound may have in relation to the parent compound and still be considered a "derivative" as intended by Applicant. Applicant has failed to provide any specific definition for this term in the present specification. Lacking a clear meaning of the term "derivative", the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection.

In the present specification at page 4, line 23, line 31, Applicant has set forth: "One preferred collagen derivative gelatin, another preferred collagen derivative, atelocollagen, and a non-cytotoxic crosslinking agent."

Such disclosure, however, does not render the claims definite. Words and phrases in the claims must be given their "plain meaning" as understood by one having ordinary skill in the art unless defined by applicant in the specification with "reasonable clarity, deliberateness and precision" (MPEP §2111.01). Here, the disclosure lacks a definition for the term "derivative" and does not set forth in a reasonably clear, deliberate or precise manner what other compounds may be considered collagen derivatives. That is, there is no limiting definition provided for this term. Thus, the identity of those compounds that are included or excluded by the "collagen derivative" is open to

subjective interpretation and such is inconsistent with the tenor and express requirements of 35 U.S.C. §112, second paragraph.

With regards to kit claims

Claims 22-24 are rejected because it is syringe with the composition. The "for use..." indicates a result of use and does not affect any part of the kit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al (US Patent No. 5972366) in view of Wallace et al (US Patent No. 6063061).

Haynes et al in their invention teach the method of making an implantable absorbable sponge suitable for implantation in the bone. The material contains drug that upon application to a surgical site or wound the material releases the drug to the surrounding tissue. The implant is used in surgical or dental procedures to provide pain relief, to control inflammation, infection and bleeding, to accelerate tissue or bone regrowth (col.3, lines 15-35).

Haynes et al further discusses the composition of the carrier and the cross-linked agents made of collagen, gel, gelatin, and oxidized cellulose (col. 4, lines 24-29). The carrier may be sized and shaped in any manner suitable for the particular body cavity or

tissue to which it will be applied. For implantation, the carrier matrix should be biodegradable and non-allergenic (col.5, lines 23-37). The resulting product can be introduced into tooth sockets after tooth extraction for drug delivery. The material can be removed days after surgery or a gum flap can be sewn over, which will eventually be resorbed (col.11, lines 54-62).

Wallace et al teaches the method for liquefying the gelatin and the gel particles were loaded into syringes. The gels were then extruded from a syringe using normal manual pressure (col.14, lines 47-54). Thus, the claimed method was within the ordinary skill in the art to make and use at the time it was made and was as a whole, prima facie obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication should be directed to Zohreh Vakili, telephone number 571-272-3099. The examiner can normally be reached from 8:30 a.m. to 6:00 p.m., Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-directouspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Examiner
Zohreh Vakili
Art Unit 1614

February 2, 2006

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